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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,009	12/22/1999	JEONG S. LEE	003764.P006	5656

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EXAMINER

LAM, ANN Y

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 03/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/470,009

Applicant(s)

LEE ET AL.

Examiner

Ann Y. Lam

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-56 is/are pending in the application.
- 4a) Of the above claim(s) 27-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-26 and 39-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 11-26 and 39-56, drawn to a catheter and mandrel, classified in class 604, subclass 164.01.
- II. Claims 27-38, drawn to a method for making a mandrel, classified in class 425, subclass 131.1.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another materially different process, for example, milling.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Suk Lee on March 15, 2002, a provisional election was made with traverse to prosecute the invention of the mandrel and catheter,

claims 11-26 and 39-56. Affirmation of this election must be made by applicant in replying to this Office action. Claims 27-38 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

Claims 40-50 and 52-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40 through 44 claims a "catheter", see line 1 of each of claims 40 through 44. However, claims 40 through 44 are dependent on claim 39, which claims a "mandrel", see line 1. It is unclear whether Applicant is claiming a mandrel or a catheter in claims 40 through 44.

Similarly, claims 46 through 50 claim a "catheter", see line 1 of each of claims 46 through 50. However, claims 46 through 50 are dependent on claim 45, which claims a "mandrel", see line 1. It is unclear whether Applicant is claiming a mandrel or a catheter in claims 46 through 50.

Likewise, claims 52 through 56 claim a "catheter", see line 1 of each of claims 52 through 56. However, claims 52 through 56 are dependent on claim 51, which claims a "mandrel", see line. It is unclear whether Applicant is claiming a mandrel or a catheter in claims 52 through 56.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 11, 13, 16-18, 39, 42-45, 48-51 and 54-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Shank et al., 5,147,317. Shank et al. discloses a mandrel (10) comprised of a variable stiffness, non-metal material, see column 7, line 5, said mandrel uniformly tapered (34) from a proximal section to a distal section, and said mandrel adapted to reinforce a catheter.

As to claims 13, 44, 50 and 56, a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel, see Figure 2.

As to claims 16, 42, 45, 48 and 55, said mandrel (10) is capable of being formed by annealing to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

As to claims 17, 39 and 54, said mandrel (10) is capable of being formed by necking at high temperatures such that said proximal section is stiffer than said distal section.

As to claims 18, 43, 49 and 51 said mandrel (10) is capable of being formed by taper extruding such that said proximal section is stiffer than said distal section.

2. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Hibbs et al., 4,950,257. Hibbs et al. discloses a mandrel (20), comprised of a variable stiffness, non-metal material, said mandrel uniformly tapered from a proximal section to a distal section, and said mandrel adapted to reinforce said catheter. The material is polyamide, see column 2, line 16.

***Claim Rejections - 35 USC § 103***

3. Claims 11-26 and 39-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus et al., 5,246,420, in view of Lorenzo, 5,836,892.

Kraus et al. discloses a catheter (14) comprising a mandrel (11) comprised of a variable stiffness material, said mandrel uniformly tapered, see column 7, line 57, from a proximal section to a distal section, see Figure 1B, said mandrel adapted to reinforce said catheter.

As to claims 13, 21, 44, 50 and 56, a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel, see Figure 1B.

As to claims 14, 22, 40, 46 and 52, the catheter comprises an inflatable member (10) comprising a proximal portion and a distal portion, wherein said distal section of

said mandrel (11) extends past said proximal portion of said inflatable member, see Figure 1B.

As to claims 15, 23, 41, 47 and 53, said distal section of said mandrel (11) extends past said distal portion of said inflatable member, see Figure 1B.

As to claims 16, 24, 42, 45, 48 and 55, said mandrel (11) is capable of being formed by annealing to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

As to claims 17, 25, 39 and 54, said mandrel (11) is capable of being formed by necking at high temperatures such that said proximal section is stiffer than said distal section.

As to claims 18, 26, 43, 49 and 51 said mandrel (11) is capable of being formed by taper extruding such that said proximal section is stiffer than said distal section.

As to claim 19, Kraus et al. discloses an outer member (14); a hollow inner member (11) extending through said outer member; an outer lumen (17) between said inner and outer members; and a mandrel extending through said outer lumen, said mandrel comprised of a variable stiffness material, said mandrel uniformly tapered, see column 7, line 57, from a proximal section to a distal section, see Figure 1B, and said mandrel is adapted to reinforce said catheter.

However, Kraus et al. does not disclose that the mandrel is formed of a non-metal material, nor specifically polyimide material.

Lorenzo discloses a tapered core wire formed of polyimide material, see column 1, lines 55-56. The core wire is equivalent to a mandrel. It would have been obvious to



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one of ordinary skill in the art at the time the invention was made to form the Kraus et al. mandrel from polyimide material, as taught by Lorenzo, as a known material used to form mandrels.


### **Conclusion**


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Imran et al., 5,520,645, discloses a mandrel with a polyimide covering.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703)308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.   
March 21, 2002

  
ANH TUAN T. NGUYEN  
PRIMARY EXAMINER  
3/22/02